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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,704	02/05/2004	George C. Tsokos	Army 178	5604

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NASH & TITUS, LLC
21402 UNISON RD
MIDDLEBURG, VA 20117

EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,704	TSOKOS ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *4,6,8,9,12-14 and 16-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,10,11,15 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04; 09/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-3, 5, 7, 10-11, 15 and 28, in the reply filed on 08/09/2005 is acknowledged. The traversal is on the ground(s) that a search of group V would necessarily include a search for the subject matter of group I and that therefore no additional burden would be created for the Patent Office. This is not found persuasive because Applicant has elected group I and a search of group I would not necessarily include a search for the subject matter of group V. Moreover, a search of the inventions of groups I and V together would present an undue burden on the Office in terms of both search and examination, as set forth in the Action mailed 8/9/05 (see pg. 5).

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

2. Claims 1-28 are pending in this application. Claims 4, 6, 8, 9, 12-14 and 16-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/09/2005. claims 1-3, 5, 7, 10-11, 15 and 28 are currently under examination in this Application.

Information Disclosure Statement

3. The information disclosure statement filed 02/05/2004 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application No. 60/445,397, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Provisional Application No. 60/445,397 does not disclose or contemplate the method of treatment of group I that comprises administration of gene modified T cells to a patient. If Applicant believes that support for the instantly claimed methods of administering

gene modified T cells to a patient is provided in the claimed priority documents, Applicant is requested to point out, with particularity, where such support is to be found. Absent this, the effective filing date of the instant Application is considered to be the instant filing date, 02/05/2004.

Information Disclosure Statement

5. The listing of references in the specification (pgs. 39-44) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been listed on the PTO Form 1449's filed 02/05/04 or 09/24/04 or have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

6. Claim 1 is objected to because of the following informalities: Claim 1 recites, "A method of a treating" which appears to be a typographical error. Appropriate correction is required.

7. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 is drawn to the

method of claim 1 wherein the patient is a human and therefore, fails to limit the method of claim 1 systemic lupus erythematosus is a human autoimmune disease.

8. Claims 7 and 28 are objected to because of the following informalities: Claims 7 and 28 depend from withdrawn claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3, 5 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terminology "having suppressed expression" and "thereby increasing the expression" in claim 1, "having suppressed expression" in claim 3 and ""that have decreased cAMP response element modulator mRNA" in claim 15 is relative terminology which renders each of these claims indefinite. The terminology is not defined by each of the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as set forth in the instant claims. The skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology, without assumption, because there is no context for determining what a suppressed level of expression would be, for example, because there is no context established for what would constitute a normal or "unsuppressed"

level, for example. Claims 2 and 5 are rejected due to their dependence on an indefinite claim.

11. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the abbreviation, "CREM" in line 2 and no assumption can be made as to what this abbreviation is intended to distinctly claim. Inclusion of a text description immediately preceding the first occurrence of the above mentioned abbreviation would be remedial in overcoming the rejection of all claims on these grounds.

12. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 depends from a withdrawn claim and is drawn to a method, "further comprising...". Therefore, because the claim depends from a withdrawn claim, the skilled artisan cannot determine the metes and bounds of what is being claimed by a method further comprising where the method is not itself claimed, without assumption.

13. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites, "A method of treating a patient with systemic

lupus erythematosus comprising" and then lists a number of steps a-d. However, the skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology because, while the claim language defines the population to be treated, it does not set forth what treatment is being provided and no assumption can be made that it is a treatment for systemic lupus erythematosus because the method is a method of treating a patient with systemic lupus erythematosus. Claim 11 is rejected due to its dependence on an indefinite claim.

14. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites, "wherein said antisense cAMP response element modulator, is a-antisense cAMP response element modulator." However, the skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology, without assumption. Does this terminology refer to an a modification of the antisense, for example? Does this terminology refer to a cAMP response element modulator protein isoform that the antisense is directed to, for example. There is no way to determine, with particularity, the subject matter which applicant regards as their invention.

15. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "The method of treating a

human patient" in line 1. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "said T cells" in 2. There is insufficient antecedent basis for this limitation in the claim.

17. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 depends from a withdrawn claim and is drawn to a method, "further comprising...". Therefore, because the claim depends from a withdrawn claim, the skilled artisan cannot determine the metes and bounds of what is being claimed by a method further comprising where the method is not itself claimed, without assumption.

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-3, 5, 10-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims are drawn to a method of treating a systemic lupus erythematosus patient comprising administering gene modified T cells having suppressed expression of cAMP response element modulator to said patient thereby increasing expression of IL-2 (claim 1) wherein said gene modified T cells are from said patient (claim 2) wherein said T cells have been treated with antisense CREM (reasonably interpreted here as antisense cAMP response element modulator although the claim terminology as presented is considered indefinite for the reasons set forth above) (claim 3), wherein said patient is a human (claim 5), to a method of treating a systemic lupus erythematosus patient comprising steps a-d as recited in claim 10 wherein the lymphocytes are transfected with plasmid vectors containing antisense cAMP response element modulator that is a-antisense cAMP response element modulator (claim 11) and to a method of treating a human patient having systemic lupus erythematosus comprising administering "said T cells" to said patient (claim 15

Claims 1-3 and 5 read broadly on a method that functions to provide a treatment for systemic lupus erythematosus, in vivo, in a patient (a human) by administering gene modified T cells, which could be any type of T-cells having any type of gene modification, wherein said T cells have been treated with antisense CREM, which is reasonably interpreted here as an antisense nucleotide sequence that inhibits the

expression of cAMP response element modulator although the claim terminology as presented is considered indefinite and is therefore considered to read on any antisense nucleotide sequence to any cAMP response element modulator. The phrase, "having suppressed expression of cAMP response element modulator" is not limiting because "having" is reasonably interpreted here, in the context of the invention and claim, as "comprising." Claims 10 and 11 are broadly drawn to an ex vivo method of treating systemic lupus erythematosus comprising removing lymphocytes from a patient, leukopheresing said lymphocytes, transfecting said lymphocytes with antisense cAMP response element modulator, wherein said antisense cAMP response element modulator is a-antisense cAMP response element modulator and reinfusing said transfected lymphocytes into said patient. Claim 15 reads broadly on a method of treating a human having systemic lupus erythematosus by administering "said T cells.

The specification provides no definition of the claimed antisense cAMP response element modulator and no guidance with regard to what is encompassed by antisense cAMP response element modulator. The specification discloses the general teaching of using sense and antisense CREM plasmids and antisense a-CREM plasmids (description of which by construction or nucleotide sequence information could not be located in the specification as filed) in vitro, in systemic lupus erythematosus T cells , normal T cells and Jurkat cells, to assay expression of CREM and determine the relationship of CREM expression to the expression of IL-2. The specification provides no disclosure of a method of ex vivo treatment using any type of gene modified T-cells that are removed from a systemic lupus erythematosus patient and reinfused or

obtained from some other source and infused into the systemic lupus erythematosus patient. The specification as filed provides examples of any types of treatment for systemic lupus erythematosus, in vivo, in any animal or in a human that is related to IL-2 and provides no evidence of any correlation between reduced expression of IL-2 in T cells in vitro and a treatment for systemic lupus erythematosus, in vivo, in any animal or in a human. The specification speculates, on pg. 25, that " it is possible that oligonucleotides with anti-sense CREM activity that can enter readily T cells will be designed and will be used to increase the production of IL-2 when desired" but provides no disclosure of such an oligonucleotide with antisense CREM activity that can readily enter T cells or how that would be used to modify T cells which would then be used to provide a treatment for systemic lupus erythematosus. The specification also notes that "The fact that CREM is expressed in various tissues may limit its controlled suppression but anti-sense oligonucleotides that target their effect to CREM expressed in lymphoid cells would be desirable," thereby pointing to a known problem in the art of antisense gene expression, that a gene to be inhibited can be expressed in various tissues wherein repression of that gene is not desired and speculating that the provision of a cell specific effect, that of antisense inhibition of CREM in lymphoid cells, would be desirable. However, the specification provides no disclosure of a treatment for systemic lupus erythematosus that provides such a cell specific effect and no disclosure that would reasonably lead one of skill to an in vivo method of administering gene modified T cells to a patent such that a treatment effect was achieved.

Applicant, therefore, has claimed a method of achieving a biological effect but has disclosed no methods that achieve that effect and provided no teaching or guidance as to how the skilled artisan would practice the instant methods, commensurate with what is now claimed, to provide an in vivo treatment for systemic lupus erythematosus. Applicant has only provided an invitation for further experimentation to determine if T cells that are modified with antisense cAMP response element modulator to that IL-2 expression is increased, could be used in the method of treatment as claimed. Applicant has not provided an adequate written description that indicates that applicant was in possession of a method of treatment because said method of treatment relies on the function of gene modified T cells or the function of antisense cAMP response element modulator, for which a structure that corresponds with said function is not adequately described; i.e., any gene modified T cells that have suppressed expression of cAMP response element modulator or any antisense CREM or cAMP response element modulator or a-antisense cAMP response element modulator, that would function to cause an increase in IL-2 expression in T-cells such that the gene modified T cells that have suppressed expression of cAMP response element modulator could be used to provide the treatment as claimed.

MPEP § 2163[R-2] I. states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.
>
> The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at

1563-64, 19 USPQ2d at 1117.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of what is now claimed. Applicant has not shown how the invention was "ready for patenting" such as by the disclosure of a representative number of species of methods that administer any gene modified T cells that have suppressed expression of cAMP response element modulator or any antisense CREM or cAMP response element modulator or a-antisense cAMP response element modulator to T cells ex vivo, that would function to cause an increase in IL-2 expression in said T-cells such that the gene modified T cells that have suppressed expression of cAMP response element modulator, that will function commensurate with what is now claimed, i.e., could be used to provide an in vivo treatment for systemic lupus erythematosus, or by describing

distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genera as claimed.

20. Claims 1-3, 5, 10-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

In the instant case, claims 1-3, 5, 10-11 and 15 are broadly drawn to subject matter that has not been adequately described in the specification such that one of skill in the art can neither determine the metes and bounds of what is now claimed nor clearly recognize that Applicant was in possession of the invention, the nature of which is a method of ex vivo gene therapy, commensurate with what is now claimed (as outlined in previous rejections herein). Given the lack of definiteness in the claims and the lack of written description in the specification, although the level of ordinary skill in

the art is acknowledged as quite high, one of skill would still require specific guidance to enable the practice of the claimed in vivo methods of treatment, with the resultant specified biological effect of treating systemic lupus erythematosus. However, the specification does not provide the requisite guidance such that any person skilled in the art would be able to practice the claimed methods without performing undue *de novo* trial and error experimentation. This experimentation would be required, at least, to identify and characterize the vast number of gene modified T cells that have suppressed expression of cAMP response element modulator, for any reason (claim 1), identify and characterize any antisense cAMP response element modulator that will function to inhibit the expression and would also include all experimentation necessary to determine, at a minimum an effective dosage and method of administration of the required gene modified T cells that have been shown to exhibit the desired increased expression in vivo, of IL-2, for a sufficient amount of time to provide a treatment for systemic lupus erythematosus, in vivo, in a patient (human).

The disclosure of the specification provides information concerning the biological effects of inhibiting cAMP response element modulator in systemic lupus erythematosus T cells on the expression of IL-2. This disclosure provides a starting point for a series of experiments that would be required to determine how to formulate a method of ex vivo gene therapy to provide a treatment as claimed. Therefore, applicant has only provided an invitation for further experimentation, since the specification is entirely prophetic in regards to a method of treatment as claimed, and provides no specific guidance for determining how the skilled artisan would practice the method treatment of the instant

invention. The specification is entirely silent on methods of ex vivo treatment and provides no guidance whatsoever as to how such a method could be practiced in vivo in a patient (human).

In particular, the specification discloses that the gene modified T cells of the invention are transformed with plasmids using electroporation (pg. 11). However, the state of the art, as exemplified by Tenbrock et al, 2002 (as referenced on the Form PTO-1449 filed 9/24/05 with this Application), recognizes, in regards to the use of antisense cAMP response element modulator in vitro to inhibit IL-2 gene expression in T-cells, that even though the idea of eliminating transcriptional repressors to increase the expression of agent that is important in may clinical conditions is appealing, "electroporation, which was sued to insert the antisense plasmid into primary SLE T cells , cannot be used currently in clinical practice." Therefore, the only mode of making gene modified T cells that are required by the instant methods, or of inhibiting cAMP response element modulator expression in T cells, as required by the instant invention, that is contemplated by the instant specification is one that is not suitable for the methods of treatment as claimed.

Thus, the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of skill in the art could not practice the methods of treating systemic lupus erythematosus, as claimed, by ex vivo gene therapy, without undue, *de novo* trial and error experimentation. In the instant case, although the type of experimentation required to

practice the invention more broadly than is exemplified is a factor in the enablement analysis, but is not dispositive. Even if the nature of each experiment required to expand the scope of the enabled invention was considered standard (which in this case it is not), it would be out weighed by the sheer quantity of experimentation required to enable the instant invention.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba